



49076.000004.UTL2  
U.S. PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	)	Group Art Unit: 1642
LEDBETTER	)	Examiner: Helms, Larry Ronald
Serial No.: 10/053,530	)	Confirmation No.: 8993
Filed: January 17, 2002	)	
For: BINDING DOMAIN	)	
IMMUNOGLOBULIN FUSION	)	
PROTEINS	)	

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)(3)

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In compliance with Applicant's duty under 37 C.F.R. § 1.97-98, the following information is brought to the attention of the Examiner. The items are listed on the attached form PTO/SB/08 and copies are enclosed for the convenience of the Examiner. Please note, some of the references listed on the accompanying PTO/SB/08 form have come to applicant's attention in a communication from a foreign patent office (International Search Report attached hereto, as well as a European Search Report) in a counterpart foreign application. Applicant is submitting the International Search Report and the European Search Report from the International Searching Authorities for this purpose.

The items identified in this Information Disclosure Statement may or may not be "material" pursuant to 37 C.F.R. § 1.56 and the submission thereof by Applicant shall not be construed as an admission that any such patent, publication or other information referred to

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therein is material or considered to be material (37 C.F.R. § 1.97(h)), or even qualified as "prior art" under 35 U.S.C. § 102 with respect to this invention unless specifically designated by Applicant as such.

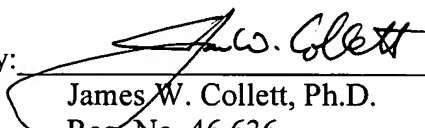
The attached Information Disclosure Statement is being filed in accordance with 37 CFR §§ 1.97(c) and 1.98. This Information Disclosure Statement is being filed after an action on the merits but before a Final Action under § 1.113 or a Notice of Allowance under § 1.113.

The fee of \$180.00, pursuant to 37 CFR § 1.17(p) is due in connection with this filing. The Commissioner is authorized to debit this amount and any additional fees required by this paper or credit any overpayment to Deposit Account No. 02-4553.

Respectfully submitted,

BUCHANAN INGERSOLL L.L.P.

By:

  
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06-07-04

DPO/21 GP1642  
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PTO/SB/21 (02-04)

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**TRANSMITTAL  
FORM**

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Total Number of Pages in This Submission

26

Application Number	10/053,530
Filing Date	January 17, 2002
First Named Inventor	LEDBETTER
Art Unit	1642
Examiner Name	Helms, Larry Ronald
Attorney Docket Number	49076.000004.UTL2

**ENCLOSURES (Check all that apply)**

- |  |   |   |
|--|---|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form                     | <input type="checkbox"/> Drawing(s)   | <input type="checkbox"/> After Allowance communication to Technology Center (TC)        |
| <input type="checkbox"/> Fee Attached  | <input type="checkbox"/> Licensing-related Papers                                       | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences     |
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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	James W. Collett, Ph.D.
Signature	
Date	May 24, 2004

**CERTIFICATE OF TRANSMISSION/MAILING**

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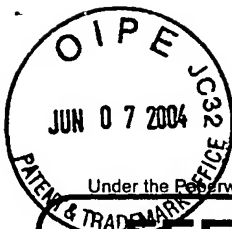
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

(\$)180.00**Complete if Known**

Application Number	10/053,530
Filing Date	1/17/02
First Named Inventor	LEDBETTER
Examiner Name	HELMG
Art Unit	1642
Attorney Docket No.	49076.000004.072.2

**METHOD OF PAYMENT** (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit Account Number: 02-4553  
Deposit Account Name: BUCHANAN INGERSOLL P.O.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$)

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION** (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	180.00
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

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**SUBMITTED BY**

(Complete if applicable)

Name (Print/Type)	JAMES W. COLLETT, Ph.D.	Registration No. (Attorney/Agent)	46,636	Telephone	(819) 578-5000
Signature	<i>J. W. Collett</i>	Date	5-24-04		

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		<b>Application Number</b>	10/053,530		
		<b>Filing Date</b>	1/17/02		
		<b>First Named Inventor</b>	Ledbetter		
		<b>Group Art Unit</b>	1642		
		<b>Examiner Name</b>	Helms		
<b>Sheet</b>	1	<b>of</b>	5	<b>Attorney Docket Number</b>	49076.000004.UTL2

U. S. PATENT DOCUMENTS						
Examine Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A.	5,098,833		LASKY et al.	03/24/92	
	B.	5,260,203		LADNER et al.	11/09/93	
	C.	5,434,131		LINSLEY et al.	07/18/95	
	D.	5,455,030		LADNER et al.	10/03/95	
	E.	5,521,288		LINSLEY et al.	05/28/96	
	F.	5,580,756		LINSLEY et al.	12/03/96	
	G.	5,605,690		JACOBS et al.	02/25/97	
	H.	5,637,481		LEDBETTER et al.	06/10/97	
	I.	5,709,859		ARUFFO et al.	01/20/98	
	J.	5,714,147		CAPON et al.	02/03/98	
	K.	5,770,197		LINSLEY et al.	06/23/98	
	L.	5,773,253		LINSLEY et al.	06/30/98	
	M.	5,844,095		LINSLEY et al.	12/01/98	
	N.	5,869,049		NOELLE et al.	02/9/99	
	O.	5,876,718		NOELLE et al.	03/02/99	
	P.	5,916,560		LARSEN et al.	06/29/99	
	Q.	6,087,329		ARMITAGE et al.	07/11/00	
	R.	6,090,914		LINSLEY et al.	07/18/00	
	S.	6,194,551 B1		IDUSOGIE et al.	02/27/01	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/053,530		
		Filing Date	1/17/02		
		First Named Inventor	Ledbetter		
		Group Art Unit	1642		
		Examiner Name	Helms		
Sheet	2	of	5	Attorney Docket Number	49076.000004.UTL2

U. S. PATENT DOCUMENTS					
Examine Initials*	Cite No. <sup>1</sup>	U.S. Patent Document	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

	T.	6,264,951 B1		ARMITAGE et al.	07/24/01	
	U.	6,312,692 B1		NOELLE et al.	11/06/01	
	V.	6,376,459 B1		ARUFFO et al.	04/23/02	
	W.	6,384,198 B1		DIEGEL et al.	05/07/02	
	X.	6,410,319 B1		RAUBITSCHKE et al.	06/25/02	
	Y.	6,444,792 B1		GRAY et al.	09/03/02	
	Z.	6,472,510 B1		ARUFFO et al.	10/29/02	
	AA.	6,623,940 B1		LEDBETTER et al.	09/23/03	
	AB.	6,641,809 B1		LINSLEY et al.	11/04/03	
	AC.	2001/004135 A1		STAHL et al.	11/22/01	
	AD.	2002/0031510 A1		LARSEN et al.	03/14/02	
	AE.	2002/0039557 A1		WHITE	04/04/02	
	AF.	2002/0155604 A1		LEDBETTER et al.	10/24/02	
	AG.	2003/0219436 A1		LEDBETTER et al.	11/27/03	
	AH.	2003/0219446 A1		LINSLEY et al.	11/27/03	
	AI.	2003/0219876 A1		LEDBETTER et al.	11/27/03	
	AJ.	2004/0058445 A1		LEDBETTER et al.	03/25/04	

FOREIGN PATENT DOCUMENTS								
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		Office <sup>3</sup> known)	Kind Code <sup>5</sup>	Number <sup>4</sup> (if				

	AK.	WC	92/00092		BRISTOL-MYERS SQUIBB COMPANY	01/09/92		
	AL	WC	93/00431		BRISTOL-MYERS SQUIBB COMPANY	01/07/93		
	AM	WC	99/42077		XCYTE THERAPIES, INC.	08/26/99		

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				<b>Complete if Known</b>	
				<b>Filing Date</b>	1/17/02
				<b>First Named Inventor</b>	Ledbetter
				<b>Group Art Unit</b>	1642
				<b>Examiner Name</b>	Helms
<b>Sheet</b>	3	<b>of</b>	5	<b>Attorney Docket Number</b>	49076.000004.UTL2

/	AN	EP	0 555 880 A2		BRISTOL-MYERS SQUIBB COMPANY	08/18/93		
/	AO	EP	0 757 099 A2		BRISTOL-MYERS SQUIBB COMPANY	07/21/95		
/	AP	EP	0 682 039 A1		BRISTOL-MYERS SQUIBB COMPANY	11/15/95		
/	AQ	EP	1 186 300 A1		BRISTOL-MYERS SQUIBB COMPANY			

#### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		AICHER, et al., "Characterization of Human Inducible Costimulator Ligand Expression and Function", The Journal of Immunology, 2000, 164: 4689-4696	
		CARTER, "Improving the Efficacy of Antibody-Based Cancer", Nature, November 2001, Volume 1, 118-129	
		CLARK et al., "Structure, Function, and Genetics of Human B Cell-Associated Surface Molecules", Advances in Cancer Research, Vol. 52, 81-149	
		DAMLE, et al., "Direct helper T cell-induced B cell differentiation involves interaction between T cell antigen CD28 and B cell activation antigen B7", Eur. J. Immunology 1991; 21; 1277-1282	
		DAVIES, et al., "'Camelising' Human Antibody Fragments: NMR Studies on VH Domains," FEBS Letters 339 (1994) 285-290	
		DESMYTER et al., "Crystal structure of a camel single-domain V <sub>H</sub> antibody fragment in complex with lysozyme", Nature Structural Biology, Volume 3, Number 9, September 1996, 803-811	
		DIETSCH et al., "Coengagement of CD2 with LFA-1 or VLA-4 by bispecific ligand fusion proteins primes T cells to respond more effectively to T cell receptor-dependent signals, Journal of Leukocyte Biology, Volume 56, October 1994, 444-452	
		DIETSCH et al., "Bispecific receptor globulins, novel tools for the study of cellular interactions", Journal of Immunological Methods, 162 (1993) 123-132	
		DURIE et al., "Prevention of Collagen-Induced Arthritis with an Antibody to gp39, the Ligand for CD40", Science, Vol. 261, September 3, 1993, 1328-1330	

<b>Examiner Signature</b>		<b>Date Considered</b>	
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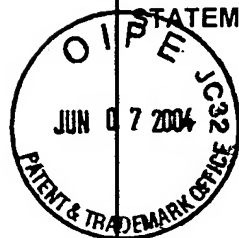


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Sheet	4	5	Attorney Docket Number	49076.000004.UTL2	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
		FELL et al., "Genetic Construction and Characterization of a Fusion Protein Consisting of a Chimeric F(ab') with Specificity for Carcinomas and Human IL-2", The Journal of Immunology, Vol. 146, 2446-2452, No. 7, April 1, 1991		
		FILPULA et al., "Single-chain Fv designs for protein, cell and gene therapeutics" Exp. Opin. Ther. Patents (1999) 9 (3):231-245		
		GILLILAND et al., "Rapid and Reliable Cloning of antibody Variable Regions and Generation of Recombinant Single Chain Antibody Fragments", Tissue Antigens 1996: 47: 1-20 (Denmark)		
		HAYDEN, et al., "Antibody Engineering," Curr. Opin. Immuno., 9:201-212 (1997)		
		HAYDEN, et al., "Single-chain Mono- and bispecific Antibody Derivatives With Novel Biological Properties and Antitumor Activity from a COS Cell Transient Expression System," Thera. Immuno., 1:3-15 (1994)		
		HAYDEN et al., "Costimulation by CD28 sFv expressed on the tumor cell surface or as a soluble bispecific molecule targeted to the L6 carcinoma antigen", Tissue Antigens 1996: 48; 242-254		
		HU, et al., "Minibody: A Novel Engineered Anti-Carcinoembryonic Antigen Antibody Fragment (Single-Chain Fv-CH3) Which Exhibits Rapid, High-Level Targeting of Xenografts," Cancer Res. 56(13):3055-3061 (1996)		
		HUDSON, "Recombinant antibodies: a novel approach to cancer diagnosis and therapy", Exp. Opin. Invest. Drugs (2000) 9(6):1231-1242		
		HUDSON, "Recombinant antibody fragments", Current Opinion in Biotechnology, 1998, 9:395-402		
		KORTT, et al., "Dimeric and Trimeric Antibodies: High Avidity scFvs for Cancer Targeting," Biomole. Eng., 18:95-108 (2001)		
		LEE et al., "Generation and characterization of a novel single-gene-encoded single-chain immunoglobulin molecule with antigen binding activity and effector functions", Molecular Immunology 36 (1999) 61-71		
		LI, et al., "Single-chain antibodies against human insulin-like growth factor I receptor: expression, purification and effect on tumor growth", Cancer Immunol. Immunother (2000) 49:243-252		

Examiner Signature		Date Considered	
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Substitute for form 1449B/PTO		<b>Complete if known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Application Number</b>	10/053,530
		<b>Filing Date</b>	1/17/02
		<b>First Named Inventor</b>	Ledbetter
		<b>Group Art Unit</b>	1642
		<b>Examiner Name</b>	Helms
<b>Sheet</b>	5		5
		<b>Attorney Docket Number</b>	49076.000004.UTL2

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		LIU, et al., "Production of a Mouse-Human Chimeric Monoclonal Antibody to CD20 With Potent Fc-Dependent Biological Activity," <i>J. Immunol.</i> 139(10):3521-3526 (1987)	
		MULTANI et al., "Monoclonal Antibody-Based Therapeis for Hematologic Malignancies", <i>Journal of Clinical Oncology</i> , Vol. 16, No 11 (November), 1998: pp 3691-3710	
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<b>Examiner Signature</b>		<b>Date Considered</b>	
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